EXHIBIT 7

P&G's Objections to Defendant's Trial Exhibit List[1]
The Proctor & Gamble Company, v. Teva Pharmaceuticals USA, Inc.
C.A. No. 04-940

DTX No.	Date of Doc.	Description	Bates Range	Depo. Ex. No.	ADMISSION		RESOLUTION		
					No Obj	Obj Basis	Notes	Admitted	Date
1	06/06/85	File Wrapper for US Patent No. 4,761,406		DX 1	X				
2	08/02/88	US Patent No.4,761,406 – Flora et al.	PG 0061784-61795	DX 2	X				
3	08/08/72	US Patent No. 3,683,080 - Francis		DX 8	X				
4	10/18/77	US Patent No. 4,054,598 – Blum et al		DX 9	X				
5	05/18/82	US Patent No. 4,330,537 – Francis		DX 10	X				
6	12/21/84	Patent Application Serial No. 06/684543		DX 11	X				
7	08/18/87	US Patent No. 4,687,768 – Benedict et al.		DX 12	X				
8		Handwritten Compound		DX 14		R, 106, H			
9		Handwritten Compound		DX 15		R, 106, H			

[1] Whether or not P&G has identified an objection to a document on its face, P&G reserves the right to object to any document depending upon the purpose for which it is offered, and depending on the witness through whom Teva intends to offer the document. P&G also reserves the right to object to and/or move to exclude documents following the Court's rulings on motions *in limine*, or rulings made prior to or during the trial.

R = Lacks Relevance
H = Hearsay (FRE 802)
403 = Unduly Prejudicial (FRE 403)
106 = Partial Document/Lacks Context or Foundation (FRE 106)
MD = Multiple Document
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DTX No.	Date of Doc.	Description	Bates Range	Depo. Ex. No.	ADMISSION		RESOLUTION		
					No Obj	Obj Basis	Notes	Admitted	Date
10		File Wrapper for US Patent 5,583,122		DX 16	X				
11	12/10/96	US Patent No. 5,583, 122 – Benedict et al	PG 0059952-59963	DX 17	X				
12	10/17/83	J.J. Benedict Special Products Group Biweekly Report - New Diphosphonates	PG 0058394	DX 23	X				
13		Japanese Patent No. S55-98193 (In Japanese)		DX 26		106			
14	08/18/87	US Patent No. 4,687,767 – Bosies et al.		DX 28	X				
15	09/03/68	US Patent No. 3,400,150 – Whyte et al.	TEVA R 05307-5316	DX 29	X				
16	11/22/83	US Patent No. 4,416,877 – Bentzen et al.	TEVA R 05317-5331	DX 30	X				
17	12/07/05	Pharmaceutical Compositions Containing Geminal Diphosphonates		DX 33		H, R, 106			
18		Critical Document Checklist	PG 0059513	DX 34		106, H, R, A			
19	5/29/91	Declaration Under 37 CFR 1.672 (b) of Kim William Zerby Constituting a Portion of the Testimony of Party Benedict et al	PG 0054985-54987	DX 35		106			
20	10/15/84	Retention Limit 11/1/84	PG 0058159-0058170	DX 36		106, R			
21	10/14/05	Notice of Rule 30 (b)(6) Deposition of Proctor & Gamble Company		DX 38	X				

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					No Obj	Obj Basis	Notes	Admitted	Date
22		Highlights of the P&G/HMR Risedronate Agreement	PG 0002009-0002015	DX 40		R, H, MC, LC, 106			
23		Impact of Direct-to-Consumer Advertising on Prescription Drug Spending	PG 0008100-0008110	DX 51		A, H			
24		Financials- Sum of Expenses; Royalty Payments to Merck for OAW; US Primary and Secondary Calls per CBD database	PG 0094413-94415	DX 62	X				
25		Third Preliminary Motion by Benedict et. al Under 37 C.F.R. 1.633 (c), to designate claims as not corresponding	PG 0055131-0055136	DX 100		106			
26		Fourth Preliminary Motion by Benedict et. al Under 37 C.F.R. 1.633 (c), to designate claims as not corresponding	PG 0060481-0060485	DX 101		106			
27		Final Hearing , May 12 1993 (Interference No. 102,399) – Benedict et al v. Bosies et al.	PG 0055570-0055586	DX 102		106			
28		Pleading- Notice of Rule 30 (b) (6) Deposition of Proctor & Gamble Company		DX 103	X				
29		Special Products Group Report: R&D Report		DX 104	X				

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					No Obj	Obj Basis	Notes	Admitted	Date
30		Correspondence from K. W. Buckingham to Distribution Re Agenda and Data Summaries for New Diphosphonates Selection Meeting, 2/17/86	PG 0069014-0069035	DX 105	X				
31		Study Design- Tox Screen 2-Day IV Screen	PG 0010758-0010780	DX 106		MD			
32		Correspondence from K. W. Buckingham to Distribution Re Agenda and Data Summaries for New Diphosphonates Selection Meeting, 2/17/86	PG 0066836-0066873	DX 107	X				
33		Interim Report No. 11- Comparitive I.V. Toxicity of Bisphosphonates (NE-58018) in Rats: A Screen	PG 0057030-0057085	DX 108	X				
34		Interim Report No. 2 Comparitive I.V. Toxicity of Biphosphonates (NE-58019) in Rats: A Screen	PG 0057086-0057146	DX 109	X				
35		Norwich Division- Product Development Biweekly Report (Bone Metabolism Department)	PG 0033731	DX 110	X				
36		Article by E.R. Van Beek et al. titled, " Binding and Antiresorptive Propoerties of Heterocycle-Containing Bisphosphonate Analogs: Structure-Activity Relationships	PG 0045556-0045570	DX 115		H, A			

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					No Obj	Obj Basis	Notes	Admitted	Date
37		Internal Correspondence from K. W Buckingham to New Diphosphonate Team Re Minutes of New Diphosphonate Team Meeting	PG 00075244-75249	DX 123	X				
38		2-Pyridyl HEDP	PG 0010782-10784	DX 125		106 (Portion of DTX 64)			
39		Norwich Division- Product Develoment Bi-weekly Report (Jocelyn E. McOsker)	PG 0034052	DX 126	X				
40	04/12/06	Expert Report of Jesse David				H, LC, also subject to P&G's Motion to Strike			
41		U.S. Patent No. 3,962,432			X				
42		U.S. Patent No. 4,621,077			X				
43		U.S. Patent No. 4,072,746			X				
44		U.S. Patent No. 4,057,636			X				
45		U.S. Patent No. 4,004,012			X				
46		U.S. Patent No. 3,928,369			X				
47		U.S. Patent No. 3,591,584			X				

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					No Obj	Obj Basis	Notes	Admitted	Date
48		U.S. Patent No. 3,225,054			X				
49		U.S. Patent No. 3,163,654			X				
50		U.S. Patent No. 4,473,560			X				
51		U.S. Patent No. 4,267,108			X				
52		Sigmar GroBman, Ulrich Moser, and Ernst Mutschler, Synthese Und Pharmakologische Priifing von Pyridin-Analoga des Fentanyls, Arch. Pharmazie 31 1: 1010; 1015 (1978)				106, H, A			
53	04/19/04	Paragraph IV letter from Teva			X				
54	05/25/05	P&G Responses to Teva's 1st set of Interrogatories (1-16)			X				
55	06/03/05	P&G Supplemental Responses to Teva's 1st set of Interrogatories (1-16)			X				
56	07/22/05	P&G Supplemental Responses to Teva's 1st set of Interrogatories (1-16)			X				
57	10/05/05	P&G Supplemental Responses to Teva's 1st set of Interrogatories (1-16)			X				
58	07/08/05	P&G Responses to Teva's 2nd set of Interrogatories (17-18)			X				
59	07/22/05	P&G Supplemental Responses to Teva's 2nd set of Interrogatories (17-18)			X				

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					No Obj	Obj Basis	Notes	Admitted	Date
60	7/22/05	P&G Responses to Teva's 3rd set of Interrogatories (19-20)			X				
61	10/05/05	P&G Supplemental Responses to Teva's 3rd set of Interrogatories (19-20)			X				
62		Translation of Japanese Patent 80-98,193				106, H, A			
63		Translation of W. Ploger et al., Z. Anorg. Allg. Chem., 389, 119 (1972)				106, H, A			
64		2-Pyridyl HEDP – Effect in 2-Day IV Tox Screen	PG 10782-10802		X				
65		Jocelyn McOsker Declaration Under 37 C.F.R. 1.132	PG 68943 – 68949			106			
66		US Patent No. 4,876,248			X				
67		US Patent No. 4,746,654			X				
68		Interference Proceedings for U.S. Patent No. 5,583,122			X				
69		H. Fleisch & R. Felix, Diphosphonates, Calcified Tissue Int. 27 (2): 91-94 (1979).				H, A			
70		James J. Benedict, The Physical Chemistry of the Diphosphonates – Its Relationship to Their Medical Activity, Diphosphonates and Bone Symposium CEMO (1982)				H, A			

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71		Gethin Williams & John D. Sallis, Structure-Activity Relationship of Inhibitors of Hydroxyapatite Formation, Biochem. J. 184:181-184 (1979)				H, A			
72		R.B. Barlow, Structure-activity relationships, 4 Trends in Pharmacological Sciences 109 (1979)				H, A			
73		F.H. Ebetino & S.M. Dansereau, Bisphosphonate antiresorptive structure-activity relationships, Bisphosphonate on Bones 139-153 (1995)				H, A			
74		W.K. Sietsema et. al., Anti-resorptive dose-response relationships across three generations of bisphosphonates, Drugs under Experimental and Clinical Research 15(9):389-396 (1989)				H, A			
75		E.R. Van Beek et. al, Binding and antiresorptive properties of heterocycle-containing bisphosphonate analogs: structure-Activity relationships, Bone 23(5):437-442 (1998)				H, A			
76		UK Patent Application GB 2 118 042 A				H, A			

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					No Obj	Obj Basis	Notes	Admitted	Date
77	07/17/89	Letter from William Sietsema to Rosemary Sudan Re TR/ED/RCS/9090 (Antiresorptive Dose-Response Relationships Across Three Generations of Bisphosphonates)	PG 0067118-0067149			106, A			
78		Graphs: First/Second Generation BPs	PG 0068117-0068130		X				
79	08/09/85	Norwich Product Development Biweekly Report	PG 0077088			106 (Portion of DTX 91)			
80	02/12/86	Internal Correspondence from K. W. Buckingham to Distribution Re Agenda and Data Summaries for New Diphosphonate Selection Meeting, 2/17/86	PG 78486-0078507		X				
81	01/04/84	Special Products Group Biweekly Report – D.F. Eastman	PG 0010781		X				
82		Norwich Division- Product Development Biweekly Report- Experimental Toxicology Section	PG 0010881-0010882		X				
83		Pharmacology and Toxicology Information	PG 0012648-0012677		X				
84		Norwich Division Product Development Biweekly Report: New Bisphosphonate Toxicology Program – New Compound Screening	PG 0034091		X				

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85		Norwich Division Product Development Biweekly Report: Update on TPTX Results for 3-Pyr HEDP and 3-Pyr HPDP	PG 0041844-0041846		X				
86		Special Products Group Biweekly Report: Diphosphonate Synthetic Program	PG 0058427		X				
87		Internal Correspondence from J.J. Benedict/ R. J. Sunberg to A.D. Geddes Re Interim Report on the Syntheis Program	PG0058472-0058478		X				
88		Special Products Group Biweekly Report: Diphosphonate Synthetic Program	PG 0058496		X				
89		Proposed 1985 Schedule: 2 Day IV Toxicity Screen for New Diphosphonate Compounds	PG 0066281		X				
90		TPTX Contract Protocol	PG 0073802-0073806		X				
91		Norwich Product Development Biweekly Report, James Benedict	PG 0077088-0077099		X				
92		Norwich Product Development Biweekly Report, Kent W. Buckingham	PG 0077110-0077120		X				
93		Portions of 37 C.F.R., subpart E - Interferences referred to herein (in the version that existed prior to the September 13,2004 revision);				106, A			

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					No Obj	Obj Basis	Notes	Admitted	Date
94		Handwritten Doc: Adult Rat Hepatocyte –In Vitro Toxicity	PG 10753 – PG10756		X				
95		UPDATE November 01, 2005 (CHART)	PG 10803 - PG 10804		X				
96		January 14, 1986 (TODAY) w/ notes	PG 10807		X				
97		January 14, 1986 (TODAY) w/ notes	PG 10814		X				
98		Interdepartmental Correspondence from F. H. Ebetino to k.J. Ibbotson and S. M. D'Souza re: Blind Screening of Phosphonates for Mechanism for Mechanism Studies	PG 10824		X				
99		SCHENK #25 RESULTS	PG 10834 - PG 10835		X				
100		Interdepartmental Correspondence Norwich Division to L.E. Van Petten from D.F. Eastman re: NE-58095 Toxicity	PG 12958 - PG 12968		X				
101		Bone Metabolism Department, Bone Metabolism Product Department and Medical Affairs Division Product Development – Summary Report November 18, 1987	PG 23091 - PG 23102		X				

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					No Obj	Obj Basis	Notes	Admitted	Date
102		Norwich Division – Product Development Biweekly Report Bone Metabolic Department – Superior Antiresorptive Activity for a New Diphosphonate (NE-58095)	PG 33732		X				
103		Norwich Division Product Development Biweekly Report: Update on TPTX Results for 3-Pyr HEDP and 3-Pyr HPDP, Kent W. Buckingham	PG 41844		X				
104		Norwich Division Product Development Biweekly Report: Continued Preclinical Testing of New Diphosphonates, , Kent W. Buckingham	PG 41846		X				
105		Memo from J.J. Benedict and C. M. Perkins to A.D. Geddes Re Project Proposal – Structure/Activity Study of Pyridyl Substituted Alkane-1, 1-diphosphonates	PG 46758 - PG 46765		X				
106		Interim Report No. 16 Re Comparative I.V. Toxicity of Bisphosphonates (NE-58020) In Rats: A Screen	PG 56964 - PG 5701 8		X				
107		Norwich Division (Cincinnati)- Product Development: The Interaction of Diphosphonates with Hydroxyapatite	PG 58337		X				
108		Tox Screen: 2-Day IV Screen	PG 66306 - PG 66308			106, Incomplete			

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109		Interdepartmental Correspondence from K.E. Buckingham to Distribution Re Agenda and Data Summaries for New Diphosphonate Selection Meeting, 2/17/86	PG 66836 - PG 66874		X				
110		Memo to R.P. D'Alonzo Re Proposal to Begin Development of 2-(2-pyridyl) 1-hydroxyehtane-1, 1-bis (phosphonic acid) (2-pyridyl HEDP)	PG 68065		X				
111		Geddes et al., Bisphosphonates: Structure-activity relationships and therapeutic implications	PG 68444 - PG 68485		X				
112		Correspondence from Karen Johnson to Liz Sikorski Re Compound for TPTX evaluation	PG 73881 - PG 73882		X				
113		Correspondence from Liz Sikorski to Karen Johnson Re Copy of notebook containing the study for Compounds	PG 73883 - PG 73939		X				
114		Internal Correspondence from A.D. Geddes to Distribution Re Two issues regarding diphosphonates	PG 76986 - PG 76988		X				
115		Company Expense Chart	PG 94698-705		X				
116		Actonel 2001-2014 Forecasts	PGK 4120-50		X				
117		Business Week Telephone Interview 8/22/2000	PGK 9090-108		X				

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					No Obj	Obj Basis	Notes	Admitted	Date
118		Brand: Actonel PMO	PGK 9353-63		X				
119		Correspondence from K. S. Napier Re: Risedronate Business Opportunity	PGK 9389-411		X				
120		Actonel (risedronate sodium tablets) Product Monograph	PGK 15481-541		X				
121		Fleisch, Chemistry and Mechanisms of Action of Biphosphonates		PX 6	X				
122		P&G's Initial Disclosure			X				
123		2001-02 U.S. Marketing Plan Recommendation	PG 0018299-0018335	DX 46		H, A			
124		Financials - Actonel TRx's (Retail, MO & LTC- in 000s)	PG 0078571-0078584	DX 60	X				
125		Dr. Jesse David CV				R, H, A			
126		Norwich Division – Product Development Biweekly Report: New Diphosphonates and Structure/Activity Relationships	PG 0034070	DX 129	X				
127		Coxon et al., Phosphonocarboxylate inhibitors of Rab geranylgeranyl transferase disrupt the prenylation and membrane localization of Rab proteins in osteoclasts in vitro and in vivo		DX 132		H, A			
128		Bruce Booth and Rodney W. Zemmel, *The Search for Blockbuster Drugs*, The McKinsey Quarterly (Mar. 9, 2006).	PG0187902 – PG0187905	DX 134	X				

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129		Business Week Telephone Interview	PGK00009090 - PGK00009108			MD (Repeat of DTX 117)			
130		Robert G. Cooper, Winning at New Products (3d. Ed. 2001).			X				
131		US Actonel Competitive Summary (Apr. 22, 2004)	PG0063939 - PG0063963	DX 59	X				
132		Marketing Plan Presentation	PGK00013626 - PGK00013714	DX 137	X				
133			PG0094413	DX 138	X				
134		Dr. Lenz CV				R, H			
135	6/19/1986	Objectives and Criteria for New Phosphonate Screening	PG 0094222 – 0094227			106			

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EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	Civil Action No. 04-940-JJF

THE PROCTER & GAMBLE COMPANY'S
TRIAL WITNESS LIST

The operative claims in this matter are set forth in The Procter & Gamble Company's ("P&G") First Amended Complaint, which alleged infringement of United States Patent No. 5,583,122 (the " '122 patent") by Teva Pharmaceuticals USA, Inc. ("Teva"). In response to the First Amended Complaint, Teva asserted various defenses, including non-infringement and invalidity of the '122 patent under 35 U.S.C. §§ 102, 103, and 112.

Subsequently, Teva stipulated to infringement of claims 4, 12, 14, 16, and 23 of the '122 patent. As a result, Teva's remaining defense is that the '122 patent is invalid, an issue on which Teva alone bears the initial burden of proof. Therefore, P&G has no burden of production or proof unless and until Teva meets its burden of establishing a *prima facie* case of patent invalidity. Only if Teva was able to prove a *prima facie* case would P&G be required to present rebuttal evidence that the '122 Patent is indeed valid. If Teva is unable to meet its burden, P&G would have no need to present rebuttal evidence of validity.

Thus, P&G's identification of fact and expert witnesses is based on P&G's current understanding of the arguments Teva is likely to make in attempting to establish a *prima facie*

case of invalidity, based upon the pleadings and discovery in the action to date. To the extent that Teva intends or attempts to introduce different or additional legal arguments to meet its burden of proof, P&G reserves its rights to contest those legal arguments, and to present any and all rebuttal evidence in response to those arguments.

Based on P&G's current understanding of Teva's remaining defenses, the following is a list of witnesses that P&G presently intends to call to testify at trial, either in person or by deposition, together with their respective addresses:

Witness	Address	General Description of Expert Testimony
James J. Benedict, Ph.D.	15239 West 77th Drive Arvada, Colorado 80007	

Witness	Address	General Description of Expert Testimony
John Bilezikian, M.D.	Columbia University Medical Center 630 West 168th Street New York, NY 10032	Dr. Bilezikian is expected to testify about the opinions and information set forth in his expert report, including but not limited to the background of osteoporosis and available methods for treatment in 1985, and the level of ordinary skill in the art. Dr. Bilezikian is also expected to testify that (1) the discovery of risedronate by P&G scientists in 1985 and its use to treat certain metabolic bone diseases was an important invention that fulfilled a long felt, but unsolved need at that time; (2) in conceiving of risedronate and its usefulness in treating osteoporosis and other metabolic bone diseases, P&G scientists succeeded in achieving certain objectives that others had tried, but failed to achieve; (3) the beneficial results of risedronate (e.g., its safety and efficacy) were unexpected in 1985; (4) the use of risedronate to treat osteoporosis and other metabolic bone diseases would not have been obvious to a person of ordinary skill in the art in the mid-1980s in view of the state of the art at that time; and (5) P&G's Actonel® product, which practices the patented invention, is successful at treating osteoporosis, the condition for which it is most often prescribed, and has advantages over some of the other available treatments. Dr. Bilezikian is also expected to testify that the '122 patent claims are not anticipated by or obvious in view of the '406 patent claims and that the '406 patent claims are not anticipated by or obvious in view of the '122 patent claims. Dr. Bilezikian may also offer rebuttal testimony to any opinions or other testimony offered by Teva.
Timothy B. Brown	1655 Fairway Crest Loveland, Ohio 45140	
David Eastman, Ph.D.	10640 Mill Road Cincinnati, Ohio 45240	
Lawrence Flora*	3664 Winter Hill Drive Hamilton, Ohio 45011	
Benjamin F. Floyd, Ph.D.*	15 Annadale Lane Cincinnati, Ohio 45246	

* Presently, P&G intends to offer the testimony of Dr. Floyd and Mr. Flora by deposition

Witness	Address	General Description of Expert Testimony
Charles McKenna, Ph.D.	16625 Pequeno Place Pacific Palisades, California 90272	Dr. McKenna is expected to testify about the opinions and information set forth in his expert report, including but not limited to the state of the art in the mid-1980s and the level of ordinary skill in the art. Dr. McKenna is also expected to testify that: (1) Drs. Benedict and Perkins conceived of the idea of risedronate prior to the filing of the '406 patent application and were diligent in later reducing the invention to practice; (2) the '122 patent claims are not anticipated by the '406 patent; (3) based upon the state of knowledge in the mid-1980s, none of the prior art asserted by Teva would have made it obvious to one of skill in the art to make or use risedronate for the treatment of metabolic bone diseases, such as osteoporosis; (4) the chemical structure of risedronate was not obvious in view of prior art bisphosphonates in the mid-1980s; and (5) based upon the knowledge in the art in the mid-1980s, the beneficial results of risedronate would have been unexpected. Dr. McKenna may also offer rebuttal testimony to any opinions or other testimony offered by Teva.
Jocelyn McOsker	756 Wards Corner Road Loveland, OH 45140	
Scott C. Miller, Ph.D.	University of Utah Center for Advanced Medical Technologies 729 Arapeen Drive Salt Lake City, Utah 84108	Dr. Miller is expected to testify about the opinions and information set forth in his expert report, including but not limited to the background of bone structure and the effect of osteoporosis on such structure, the state of the art in the mid-1980s, the methods for testing compounds for use as a treatment for osteoporosis, the unexpected safety and efficacy differences between risedronate and prior art bisphosphonates and the non-obviousness of the '122 patent claims in view of the prior art references cited by Teva. Dr. Miller may also offer rebuttal testimony to any opinions or other testimony offered by Teva.
Daniel Smith, Ph.D.	835 South Sheridan Drive Bloomington, Indiana 47401	Dr. Smith is expected to testify about the opinions and information set forth in his expert report, including but not limited to the commercial success of Actonel® and its relationship to the invention of the '122 patent. Dr. Smith may also offer rebuttal testimony to any opinions or other testimony offered by Teva.

Witness	Address	General Description of Expert Testimony
Jerry D. Voight, Esq.	Finnegan Henderson Stanford Research Park 3300 Hillview Avenue Palo Alto, California 94304	Mr. Voight is expected to testify about the opinions and information set forth in his expert report, including but not limited to background on patent interference practices and procedure and the applicability of the two-way test for obviousness-type double patenting under the circumstances of this case. Mr. Voight may also offer rebuttal testimony to any opinions or other testimony offered by Teva.
David Wiemer, Ph.D.	7 Heather Circle Iowa City, Iowa 52245	Dr. Wiemer is expected to testify about the opinions and information set forth in his expert report, including but not limited to the state of the art in the mid-1980s, the level of ordinary skill in the art, and the written description support in the '543 application for claims 4, 12, 14, 16 and 23 of the '122 patent. Dr. Wiemer may also offer rebuttal testimony to any opinions or other testimony offered by Teva.
Kim Zerby, Esq.	6248 Fay Court Loveland, Ohio 45140	

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE PROCTER AND GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS, INC. Defendant.	)	C.A. No. 04-940 (JJF)

TEVA USA'S WITNESS LIST

Teva USA may call the following witnesses at trial either in person or by deposition:

James Benedict
15239 West 77th Drive
Arvada, CO 80007

Timothy Brown
1655 Fairway Crest
Loveland, OH

David Eastman
10640 Mill Road
Cincinnati, OH

Benjamin Floyd
15 Annadale Lane
Cincinnati, OH 45246

David Suter
3620 Blue Heron Lane,
Rochester Hills, MI

Kim Zerby
6248 Fay Court
Loveland, OH 45140

Teva USA's Expert Witnesses

George R. Lenz, Ph.D., M.B.A.
6 Apple Blossom Road
Andover, MA 01810-5402

Dr. Lenz will testify in accordance with the expert report he submitted in this case. In addition, he may respond to the testimony presented on behalf of P&G.

Jesse David, Ph.D.
National Economic Research Associates, Inc.
1166 Avenue of the Americas
New York, NY 10036

Dr. David will testify in accordance with the expert report he submitted in this case. In addition, he may respond to the testimony presented on behalf of P&G.

EXHIBIT 10

P&G's Initial Deposition Designations and Teva USA's Objections and Counter-Designations

E = calls for expert opinion from a lay witness or from an individual that has not been identified as an expert in this action (Rule 701).
H = hearsay (Rule 801/802)
I = incomplete
L = lack of personal knowledge
O = includes objection from attorney or colloquy
N = lack of foundation (Rule 611(c))
R = relevancy (lack of)(Rule 401/402)
V = vague or ambiguous (Rule 611(a))

Deponent	P&G Designation	Objection	Teva USA Counter-Designation[1]
L. Flora	6:8-15		
L. Flora	7:2-14		
L. Flora	9:3-12:21	R	
L. Flora	13:10-14:1		
L. Flora	15:8-16:11	R	16:17-23, 18:5-12
L. Flora	20:7-9		
L. Flora	21:1-8		
L. Flora	24:7-19	R	22:24-24:6
L. Flora	25:14-18	R	25:9-13
L. Flora	26:16-29:12	E, R, O	
L. Flora	33:1-15	R, I	33:15-20, 34:11-35:14
L. Flora	36:7-9	R	

[1] The placement of a Teva USA Counter-Designation on a line in the table above does not restrict that designation as a counter to the P&G Deposition Designation on that same line above. Teva USA reserves the right to request that any of P&G's designations, or Teva USA's counter-designations be entered into evidence.

L. Flora	43:20-45:13	L, R, I	45:14-46:19
L. Flora	47:11-14	R	47:1-10, 54:19-56:5
L. Flora	59:23-60:10	E, R	
L. Flora	84:10-85:12	R	
B. Floyd	5:7-13		
B. Floyd	6:5-18:1	R, O	18:7-14
B. Floyd	22:9-22	R,O	
B. Floyd	25:3-11		
B. Floyd	25:17-27:3	R, O	
B. Floyd	33:24-35:5	I	35:6-10
B. Floyd	44:11-45:21	R, O	
B. Floyd	48:12-15	I	48:16-49:11
B. Floyd	49:12-51:8	R, O	
B. Floyd	61:13-62:15	R	71:3-71:7, 71:9-72:16, 75:7-76:9, 80:5-10, 80:12-81:23
B. Floyd	101:21-102:12	R	
B. Floyd	109:17-22	R, I	109:24-110:17

EXHIBIT 11

P&G'S OBJECTIONS AND COUNTER-DESIGNATIONS TO TEVA'S DEPOSITION TRANSCRIPT DESIGNATIONS[1]

From the deposition of Benjamin Floyd, October 11, 2005:

Page	Line	-	Page	Line	Objections	Counterdesginations
5	7	-	5	13		
6	5	-	7	15		
8	22	-	8	24		
16	14	-	17	5	17:4-5 --FM, F	17:6-7
17	8	-	18	1	17:8-9 -- FM, F	
18	7	-	18	14	18:12-14 – F	
35	6	-	35	10		34:9-24 35:1-5 35:11-17
48	16	-	49	5	F, A, H	39:8-12
49	8	-	49	11	F, A, H	49:6-7
71	3	-	71	5		71:6-8

[1] P&G reserves the right to object to any or all designations depending upon the purpose for which they are offered, and depending on the witness(es) through whom Teva intends to offer the testimony P&G also reserves the right to object to and/or move to exclude designations following the Court's rulings on motions *in limine*, or rulings made prior to or during the trial

***Legend of P&G's Objections:**

A = Lacks authenticity (FRE 901/902)

R = Lacks relevance (FRE 401/402)

H = Hearsay (FRE 802)

O = Improper opinion (FRE 701/702)

F = Lacks foundation/speculative (FRE 602)

LC = Legal conclusion

NR = Non-responsive/move to strike

P = Unduly prejudicial/confusing (FRE 403)

FM = Objection to form

Page	Line	-	Page	Line	Objections	Counterdesginations
71	9	-	72	16	72:3-8 -- FM 72:9-13 -- F 72:14-19 -- FM, F	72:17-23
80	5	-	80	10	80:5-14 -- FM, F, O	80:11
80	12	-	81	23	F, O	

***Legend of P&G's Objections:**

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From the deposition of James Benedict, Ph.D., October 17, 2005

Page	Line	-	Page	Line	Objections	Counterdesignations
7	8	-	10	3		11:18-24, 12:23-13:24, 19:11-13, 19:22-24, 20:1-7, 24:21-24, 25:1-19, 26:1-24, 27:1-22, 42:12-22, 43:8-14, 44:12-24, 45:1-3, 69:15-19
57	14	-	57	17		
57	22	-	59	8		
59	24	-	64	20		67:8-15
64	22	-	64	23		
65	16	-	65	24		
66	11	-	66	14		
99	4	-	100	9		
100	11	-	100	24	100:18-100:24 – F, O	
101	2	-	101	3	F, O	
101	21	-	102	17	102:15-17 – F, O	97:13-98:2
102	19	-	103	2	102:19 – F, O	
103	4	-	103	6		
103	8	-	103	9		

***Legend of P&G's Objections:**

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Page	Line	-	Page	Line	Objections	Counterdesignations
177	20	-	177	22		
178	4	-	179	2	178:7-179:2 – F, O	116:16-118:9
179	4	-	179	6	179:4-179:6 – F, O	
179	23	-	181	4	180:7-15 – F, O	181:5-182:12
192	13	-	193	15	193:1-15 - F	194:23-195:15

***Legend of P&G's Objections:**

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From the deposition of David Suter, Esq., October 28, 2005

Page	Line	-	Page	Line	Objections	Counterdesignations
7	22	-	8	22	R	
9	7	-	9	22		
20	18	-	21	4		
21	12	-	21	22		
24	25	-	25	5	A, R, F	
34	24	-	35	1		33:2-34:11
36	12	-	37	20		33:2-34:11
38	1	-	38	6		
39	10	-	41	22	39:10-14 – O, LC 39:15-25 – R, O, LC 40:1-22 – FM, R, P	
42	11	-	42	25	R	
45	8	-	45	15		
46	25	-	47	18	FM, R, P	47:19-22
64	16	-	66	12	FM, O, R, P	
67	7	-	67	19		
68	23	-	70	22	H, R	70:23

***Legend of P&G's Objections:**

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Page	Line	-	Page	Line	Objections	Counterdesignations
70	24	-	70	25	H, R	70:23; 72:14-17
71	2	-	72	13		
72	20	-	72	23	R	
73	4	-	73	7	R, H	
73	15	-	74	3	R, H	
74	11	-	74	17	R	
75	3	-	76	4	R	
76	6	-	76	18	R	
77	1	-	78	10	77:20-78:10 – F, R, P	
83	20	-	84	13	FM, F, R, P	
84	15	-	84	19	H, R	
85	1	-	86	16	H, R 86:5-16 – FM, F, R, P	86:14-20
86	23	-	87	12	H, R	
87	21	-	88	24	87:21-88:1 – LF, H, R, P 88:3-24 – R	
89	14	-	89	22	R	
89	25	-			R, LC	

***Legend of P&G's Objections:**

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Page	Line	-	Page	Line	Objections	Counterdesignations
90	3	-			R, LC	90:1, 4
90	5	-	90	10	FM, R, LC	90:11
90	12	-	91	4	FM, R, LC	91:5
91	6	-	91	17	FM, R, LC	91:18
91	19	-	91	24		
92	2	-	92	8	FM, F, R, P	
94	5	-	94	18	R	
95	21	-	96	14	R 96:9-14 - FM, F, R, P	112:12-113:5
96	19	-	96	21	FM, F, R, P	
97	24	-	97	25	H, FM, F, R	
98	1	-	98	15	H, FM, F, R	
99	2	-	99	4	FM, O, F, R	99:5
99	6	-			FM, O, F, R	99:5
99	8	-	99	11	FM, O, F, R, LC	99:12
99	13	-			FM, O, F, R, LC	99:12
99	15	-	99	16	FM, O, F, R, LC	99:17

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Page	Line	-	Page	Line	Objections	Counterdesignations
99	18	-			FM, O, F, R, LC	99:17
99	20	-	99	21	FM, O, F, R, LC	99:22
99	25	-			FM, O, F, R, LC	99:22
100	2	-	100	4	F, R, P	
100	7	-	100	10	F, R, P	
104	3	-	104	21	R 104:15-21 - F, R, P	112:12-113:5
105	24	-	106	6	H, O, F, R	106:7
106	8	-			H, O, F, R	106:7
106	10	-	107	6	H, O, F, R	107:7-8
107	11	-	107	14	H, O, F, R	107:7-8
107	23	-	108	5	F, R, P	
113	9	-	113	17	FM, F, R, P	112:12-113:5; 113:18-19
113	20	-	114	2	FM, F, R, P	113:18-19
122	2	-	122	12	FM, F, R	122:13
122	14	-			FM, F, R	122:13
122	16	-	122	21	FM, F, R	

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Page	Line	-	Page	Line	Objections	Counterdesignations
123	16	-	122	22	FM, F, R	
124	15	-	125	12	F, R	125:18
125	14	-				
126	12	-	126	24	FM, F, R, H	126:25
127	1	-	127	4	FM, F, R, H	126:25
127	6	-	127	10	FM, R, P (no testimony cited)	127:11
130	17	-	131	10	FM, F, R, P	
132	22	-	133	11	R	
134	3	-	134	8	R	
134	20	-	134	22	R	
135	17	-	135	23	R, H	
138	12	-	138	22	R	
167	3	-	167	23	FM, F, R, P	169:1-14

Legend of P&G's Objections:

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FM = Objection to form

From the deposition of Kim W. Zerby, Esq., December 8, 2005:

Page	Line	-	Page	Line	Objections	Counterdesignations
8	11	-	8	25		
9	13	-	9	17		
10	3	-	10	19		
12	13	-	12	25		
13	1	-	13	25		
14	1	-	15	4		
19	20	-	19	6		
22	19	-	22	21	H, R, P (no testimony)	
23	17	-	24	16	23:17-21 – R	
25	9	-	25	17	H, R	
29	20	-	29	23	FM, F, R	29:24-30:3
30	4	-	30	8		
30	12	-	30	21		
32	20	-	33	20	FM, F, R	
44	7	-	46	12	R, H, O, LC	

***Legend of P&G's Objections:**

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Page	Line	-	Page	Line	Objections	Counterdesignations
49	13	-	54	21	FM, R, F, P	54:22-55:10
55	11	-	55	17		55:18
55	20	-	55	25		55:18; 56:1
56	2	-	56	5		56:6
56	7	-	56	11		56:6
64	14	-	65	2	FM, F, H, R	
65	14	-	65	20	R, H	
66	2	-	66	20	R, H	
67	2	-	70	1	R, F, FM, P	
72	13	-	72	14	R, LC	72:15-18
72	19	-	73	24	R, LC	72:15-18
73	9	-	73	13	R, LC	
73	15	-	73	20	R, LC	
74	5	-	77	18	FM, F, R, H, LC	77:19
77	20	-			FM, F, R, H, LC	77:19
78	4	-	78	6		78:7

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Page	Line	-	Page	Line	Objections	Counterdesignations
78	8	-	78	15	FM, F, O, LC	78:7; 78:16
78	17	-	78	21	FM, F, R, LC 78:20-21 – R, P (no testimony)	
79	13	-	79	16	FM, F, R, LC	79:17
79	18	-			FM, F, R, LC	79:17
81	2	-	81	12	R	
82	3	-	83	20	FM, F, R, LC	
83	11	-	83	16	FM, F, R, LC	
84	4	-	84	20	H, R, LC	84:21-22
84	23	-	85	4	H, R, LC	84:21-22
85	6	-	85	14	FM, F, R	85:15-19
86	23	-	86	25		87:1-3
87	9	-	87	20	H, R	87:1-3; 87:21
87	22	-	87	25	FM, F, H, R	87:21
88	2	-	88	5	FM, F, R	88:1
88	8	-	88	10		88:1; 88:6-7
88	17	-	88	17	P (incomplete question)	88:21

***Legend of P&G's Objections:**

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R = Lacks relevance (FRE 401/402)

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FM = Objection to form

Page	Line	-	Page	Line	Objections	Counterdesignations
88	22	-	89	2	FM, F, R	88:21; 89:3
89	8	-	89	12	FM, F, R	89:3; 89:12
89	14	-	90	14	FM, F, R	89:12; 90:15
98	24	-	99	13	FM, F, R, H, LC	
100	17	-	102	17	FM, F, R, H	
102	19	-	103	6	R, H	
103	9	-	103	13	FM, F, R, H	103:14
193	15	-	104	1	FM, F, R, H	103:14; 104:2
104	3	-	104	8	FM, F, R, H, LC	104:2; 104:9
104	10	-	104	16	FM, F, R, H, LC	104:9; 104:17
104	18	-	104	20	FM, F, R, H, LC	104:17
107	15	-	108	2	FM, F, R, H	108:3-4
108	5	-	109	6	FM, F, R, H, LC	109:7
109	8	-	110	5	FM, F, R, H, LC	109:7; 110:6
110	7	-	110	16	FM, F, R, H, LC	110:6; 110:17
110	18	-	110	23	FM, F, R, H, LC	110:17; 110:24

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Page	Line	-	Page	Line	Objections	Counterdesignations
111	11	-	111	21	H, R, LC	
111	23	-	111	25	R	
112	13	-	112	17	R, H	
112	20	-	113	10	FM, R, H	
114	8	-	114	18	FM, F, R	114:19-22
114	23	-	116	5	FM, F, R, H, LC	
127	6	-	133	13	FM, F, R, H, LC, P	
133	15	-	134	1	R	
135	23	-	136	1	R	136:2
136	3	-	136	12	FM, R	136:2; 136:13
136	14	-	137	1	FM, R	136:13; 137:2
137	3	-	137	17	FM, R	137:2
137	23	-	138	2	R, H, A	
138	15	-	138	17	FM, F, R, H, A	138:18-19
138	20	-	139	18	FM, F, R, H, A	138:18-19; 139:19
139	20	-	139	22	FM, R	139:19

***Legend of P&G's Objections:**

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Page	Line	-	Page	Line	Objections	Counterdesignations
139	24	-			FM, F, A, H, R	139:23; 139:25-140:1
140	2	-	140	21	FM, F, A, H, R	139:25-140:1; 140:22
140	23	-	145	5	140:23- 141:15 – FM, F, R, P FM, R	140:22; 145:6-14
145	15	-			FM, R	145:6-14
149	1	-	149	3	R	149:4
149	8	-	149	23	FM, F, R, LC	149:4; 149:24-25
150	3	-	150	5	FM, F, R	149:24-25
151	6	-	151	8	FM, F, R	151:9
151	10	-			FM, F, R	151:9
206	18	-	206	24	FM, F, R	206:25-207:1
207	2	-	207	5	FM, O, F, R, LC	206:6
207	7	-	207	5	Not a proper designation	Not a proper designation
215	14	-	215	21	FM, F, R, O, LC	215:22
215	23	-	216	17	FM, F, R, O, LC	215:22

***Legend of P&G's Objections:**

A = Lacks authenticity (FRE 901/902)

R = Lacks relevance (FRE 401/402)

H = Hearsay (FRE 802)

O = Improper opinion (FRE 701/702)

F = Lacks foundation/speculative (FRE 602)

LC = Legal conclusion

NR = Non-responsive/move to strike

P = Unduly prejudicial/confusing (FRE 403)

FM = Objection to form

From the deposition of Timothy B. Brown, December 9, 2005

Page	Line	-	Page	Line	Objections	Counterdesignations
8	5	-	8	18		
9	16	-	10	13		
10	19	-	13	16	10:22-12:7—R 12:15-16—FM, F 12:23-13:2—F 13:14-16—F	
18	1	-	19	11	18:5-7—F 18:8-17--H 19:5-11—F	19:12-15
19	16	-	19	18		
19	24	-	21	5	20:22-21:5—F	21:6-11
21	12	-	22	10		22:11-23:10
28	20	-	28	22	F	
29	6	-	29	16	R, F, FM	
30	11	-	30	17		
31	5	-	31	8		31:9-22
39	22	-	39	25		
40	13	-	40	20	40:13-19—A, H, F 40:20—F	40:21
40	22	-	41	9	40:22-41:9—F	

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Page	Line	-	Page	Line	Objections	Counterdesignations
44	4	-	45	7	44:10-45:7—F	43:7-44:3 45:6-25
46	6	-	46	17	F	46:1-5 46:18-47:6 47:12-48:7
61	9	-	62	3		62:4-23
64	5	-	64	13	64:9-13--F	64:14-17
64	18	-	66	5	64:18-19—F 64:23-25—F, H 65:1-6—FM, F, R 65:14-23—F, H 65:24-66:5—F	
66	16	-	67	6	67:6—FM	66:6-15 67:7
67	10	-	69	14	68:11-23—FM 69:5-10—F 69:11-14—FM, F	69:15
69	16	-	69	20	69:16-20—FM, F	69:21
69	22	-	70	10	69:22-70-1—FM, F 70:2-10—F	70:25-71:8
75	20	-	75	22		75:23-76:11
76	17	-	78	10	76:22-77-17—F 77:18-78:6—H, F, O	78:11-25
79	1	-	80	8	79:3-18—H 79:19-23—F	80:9-81:9
106	6	-	106	19	106:6-9 – F 106:10-14 – FM	106:20-107:7
108	6	-	108	21	108:14-21 – F	108:22-109:1

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Page	Line	-	Page	Line	Objections	Counterdesignations
133	8	-	135	14	134:18-135:5 – H 135:6-14 –F	135:15-18
136	3	-	136	16	136:10-16 –F, R	
148	4	-	148	7		148:9-22
149	10	-	155	19	149:17-150:4 – F 150: 5-11 –H 150:12-151:2 – H, F, A 151:11-20 – H, F, A 152:1-5 – FM 154:3-14 – H, F, A 156:2-18 –H, F, A	
177	11	-	178	8	178:5-8 -- H	178:9-178:25
179	7	-	183	11	179:8-180:16 – H, F 181:8-17 – F, R 181:21-183: 2 – H, F 183:3-11 – F, R	179:1-7

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From the deposition of David Eastman, Ph.D., December 13, 2005

Page	Line	-	Page	Line	Objections	Counterdesignations
8	11	-	8	25		
10	2	-	12	1		12:2-8
12	9	-	13	22		
14	17	-	15	15		15:16-21; 16:23-17:7; 17:15-19
17	19	-	19	10		
21	6	-	21	10		
21	20	-	23	15		23:16
23	17	-	25	20	23:22-24:2 – F	23:16
26	15	-	26	22		
27	2	-	27	10		
29	1	-	29	14		
29	22	-	31	23		
31	25	-	35	22	32:10-15 – F, O 25:9-20 – FM 30:7-19 – F, O 31:25-32:15 – F, O	
41	7	-	41	10		

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Page	Line	-	Page	Line	Objections	Counterdesignations
41	21	-	42	7		
44	1	-	44	19		
44	21	-	44	25	44:22-45:6 – R	45:24 – 46:15
45	2	-	45	11		
45	13	-	45	23		
46	16	-	46	17		
46	19	-	47	9	47:7-9 – R, FM	
59	25	-	60	1		
60	21	-	61	2		
61	4	-	61	5		61:6 – 62:18
64	3	-	64	12	FM	
64	22	-	64	24	R, F	
65	1	-	65	5	R, F	
65	7	-	65	13	R, F, O	65:14
65	15	-	65	19	R, F, O	
93	18	-	94	3		

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Page	Line	-	Page	Line	Objections	Counterdesignations
94	13	-	95	10	R	
96	10	-	96	21	R, H, F, A	
98	17	-	99	1	R, F, FM	
99	9	-	100	19	R, F, FM	
102	15	-	102	19	R, F, FM, O	
103	2	-	103	18	R, F, FM, O	103:19
103	20	-	105	9	R, F, FM, O	103:19
105	20	-	106	2	R, F, FM, O	
106	9	-	106	15	R, F, FM, O	106:16
106	17	-	107	25	R, F, FM, O	106:16
108	2	-	108	9	R, F, FM, O	108:1
109	14	-	109	21	R, F, FM, O	109:22
109	23	-	110	2	R, F, FM, O	109:22
117	24	-	119	5		
119	17	-	119	20		
119	22	-	119	24		

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R = Lacks relevance (FRE 401/402)

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Page	Line	-	Page	Line	Objections	Counterdesignations
120	2	-	120	22		
130	25	-	131	4	R	121:9 – 122:4; 122:15 – 123:4
132	3	-	132	6	F, P	132:7
132	8	-	132	18	F, P	
132	20	-	132	21	F, P	
175	15	-	175	17		175:18 – 176:6; 176:13 – 177:16
177	17	-	178	1		
178	15	-	179	1		
180	19	-	181	11	R, F	
186	8	-	186	9	R	186:10-12; 186:18 – 197:9
187	10	-	187	16	R	
197	16	-	197	25		

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EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 04-940-JJF

BRIEF STATEMENT OF WHAT THE PROCTER & GAMBLE COMPANY INTENDS TO PROVE IN SUPPORT OF ITS CLAIMS

The operative claims in this matter are set forth in The Procter & Gamble Company's ("P&G") First Amended Complaint, which alleges infringement by Teva Pharmaceuticals USA, Inc. ("Teva") of United States Patent No. 5,583,122 (the "'122 patent"). In response to the First Amended Complaint, Teva asserted various defenses, including non-infringement and invalidity of the '122 patent under 35 U.S.C. §§ 102, 103, and 112.

Subsequently, Teva stipulated to infringement of claims 4, 12, 14, 16, and 23 of the '122 patent. As a result, Teva's remaining defense is that the '122 patent is invalid, an issue on which Teva alone bears the initial burden of proof. Therefore, P&G has no burden of production or proof unless and until Teva meets its burden of establishing a *prima facie* case of patent invalidity. Only if Teva was able to establish a *prima facie* case would P&G be required to present rebuttal evidence that the '122 patent is indeed valid. If Teva is unable to meet its burden, P&G would have no need to present rebuttal evidence of validity.

Thus, P&G's brief statement of what it intends to prove at trial in support of its claims is based on P&G's current understanding of the arguments Teva is likely to make in attempting to

establish a *prima facie* case of invalidity, based upon the pleadings and discovery in the action to date. To the extent that Teva intends or attempts to introduce different or additional arguments to meet its burden of proof, P&G reserves its rights to contest those arguments, and to present any and all rebuttal evidence in response to those arguments, and will not be bound by the summary of evidence presented herein. A brief statement describing P&G's rebuttal evidence, if necessary, is set forth below.

1. The '122 patent was filed on December 6, 1985 and is a continuation-in-part of an application filed on December 21, 1984, application Serial No. 684,543 (the "'543 application"). The '122 patent issued on December 10, 1996 with two former P&G employees, Dr. James Benedict and Dr. Christopher Perkins, as the named inventors.

2. The '122 patent has 23 claims. P&G has asserted claims 4, 12, 14, 16 and 23 against Teva. Claims 4, 16, and 23 are specifically directed to the active ingredient of P&G's Actonel® product: [2-(3-pyridyl-1-hydroxyethane diphosphonic acid] monosodium salt, also known as risedronate sodium.[1] Claim 4 is an independent claim that covers the risedronate compound. Claims 12 and 14 are directed to pharmaceutical compositions that would cover a variety of compounds including risedronate. Claim 16, which depends from claim 14, is directed to the pharmaceutical composition that is contained in Actonel®. Claim 23, which is a dependent claim, covers methods of treating diseases associated with abnormal calcium and phosphate metabolism comprising administering Actonel® to a person in need of such treatment.

3. In alleging that the asserted claims of the '122 patent are invalid, Teva primarily relies on another P&G patent, U.S. Patent No. 4,761,406 (the "'406 patent"), which was filed on June 6, 1985 and issued on August 2, 1988. The '406 patent claims a method for treating

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[1] "Risedronate" as used herein encompasses both the acid and the salt form, i.e., [2-(3-pyridyl-1-hydroxyethane diphosphonic acid] and [2-(3-pyridyl-1-hydroxyethane diphosphonic acid] monosodium salt.

osteoporosis with a polyphosphonate[2] according to a schedule of (a) administration of the polyphosphonate, (b) rest and (c) repeat. The '406 patent lists numerous bisphosphonates[3] for use in the method, including 2-(2-pyridyl)-1-hydroxyethane-1, 1-diphosphonic acid ("2-pyr EHDP").[4] Even though the '406 patent application was filed almost six months after the '543 application to which the '122 patent claims priority, Teva contends that the '406 patent is prior art to the '122 patent, and that it anticipates claims 12 and 14 of the '122 patent and renders claims 4, 16, and 23 obvious. Teva asserts that the '543 application does not have sufficient written support for the claims at issue, and that the '122 patent is therefore not entitled to the earlier priority date. Teva also contends that, even if the '122 patent is entitled to the earlier priority date, it is invalid as a result of obviousness-type double patenting.

4. P&G will present evidence and testimony that the '406 patent is not prior art. First, the '406 patent is not prior art to the asserted '122 patent because the '122 patent is entitled to the priority date of the '543 application. Teva asserts that the '543 application lacks written description support for the asserted '122 patent claims because the '543 application does not provide the identical structures or specifically name risedronate. However, the claimed compounds, including risedronate, are encompassed by the genus and subgenus structures set forth in the '543 application. P&G will present evidence that there are ample blaze marks that would lead one of ordinary skill in the art reading the '543 application to the claimed compounds, including risedronate. Second, even if the '122 patent was not entitled to the benefit of the filing date of the '543 application, the '406 patent still would not be prior art because the

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[2] A "polyphosphonate" is a compound having more than one phosphonate group ($-PO_3H_2$) as part of its molecular structure.

[3] A "bisphosphonate" is a polyphosphonate having two phosphonate groups ($-PO_3H_2$) as part of its molecular structure.

[4] Structurally, this compound differs from risedronate in that the nitrogen atom present on the pyridine ring is in a different position. In risedronate, the nitrogen atom is in the "3-position"; in 2-pyr EHDP, the nitrogen atom is in the "2-position."

risedronate compound described in and encompassed by the '122 patent claims was conceived and reduced to practice before the filing of the '406 patent application.

5. Even apart from the fact that the '406 patent is not prior art to the '122 patent, the '406 patent does not render obvious claims 4, 16, and 23 of the '122 patent – the claims that are directed to risedronate – because it would not have been obvious to one of ordinary skill in the art to modify the compounds disclosed in the '406 patent, most notably 2-pyr EHDP, to make risedronate. There is nothing in the '406 patent (or in the other prior art identified by Teva) that suggests or provides a motivation to modify 2-pyr EHDP to make risedronate or that doing so would be reasonably likely to succeed in producing a useful compound. There is no indication that such a modification would produce a compound that would be safe and effective for treatment of a disease associated with abnormal calcium and phosphate metabolism. Nor is there any indication in the '406 patent that such a modification would be otherwise advantageous. Given the poor understanding then (and now) of the relationship between bisphosphonate structure and bone activity, one of ordinary skill in the art would have had no expectation that modifying 2-pyr EHDP to form risedronate would result in a compound that had an improved, or even equivalent, safety/efficacy profile compared to 2-pyr EHDP. The unpredictability of the effect of small changes in structure on safety and efficacy of a compound was also well recognized in the art in 1984-1985. Given the unpredictability of the effect of small changes in structure of bisphosphonates, one of ordinary skill in the art in 1984-1985 would not have expected risedronate to have similar properties to other structurally-similar bisphosphonates, and as a result, the prior art bisphosphonate compounds do not render risedronate obvious. In fact, P&G researchers repeatedly discovered that small changes in structure could have significant, yet unpredictable, effects on a compound's activity.

6. Teva also has identified several other prior art patents that it claims alone, or in combination with the '406 patent, render the '122 patent obvious. For the same reasons that the '406 patent does not render the '122 patent obvious, the other prior art references also do not render the '122 patent claims obvious.

7. In addition, there is substantial objective evidence of non-obviousness of the asserted claims. Due to the unpredictability of the properties of bisphosphonates based upon their structure, the improved safety and efficacy of the claimed bisphosphonates were unexpected. In particular, P&G's testing of risedronate yielded the unexpected result that it was significantly more potent, and relatively less toxic, than other bisphosphonates that it had tested, including 2-pyr EHDP. As a result of its improved safety/efficacy profile, risedronate solved the long felt, but unmet need for a better bisphosphonate. At the time of the invention of risedronate, there were limited options available for the treatment of diseases associated with abnormal calcium and phosphate metabolism, including osteoporosis. The non-obviousness of risedronate is also evidenced by the fact that, since introduction of Actonel® in 1998, P&G has achieved commercial success, with sales of more than $2 billion, in spite of heavy competition from other osteoporosis drugs. Finally, Teva's decision to offer a generic form of Actonel® that admittedly infringes the claimed invention is further proof that the asserted claims of the '122 patent covering risedronate are non-obvious.

8. Teva's final defense is that the '122 patent is invalid as a result of obviousness-type double patenting in view of the '406 patent. To prove such a basis of invalidity, either a one- or two-way test is required.[5]

9. Here, the two-way test applies because the evidence demonstrates that P&G acted diligently throughout the examination and interference proceedings, and that the delay in the ultimate issuance of the '122 patent was solely administrative based upon the interference proceeding at the Patent Office and subsequent appeal to the Federal Circuit.

10. Applying either the one- or the two-way test, Teva cannot prove that the '406 patent claims render the '122 patent claims obvious for the reasons described above. For the two-way test, Teva further cannot prove that the '122 patent claims render the '406 patent claims obvious because the specific dosing regimen as claimed in the '406 patent is neither disclosed nor suggested by the '122 patent claims.

11. In addition, as set forth *supra*, there is substantial objective evidence of non-obviousness of the asserted claims. Thus, were Teva able to establish a *prima facie* case that the asserted '122 patent claims are invalid, P&G will present evidence and testimony to successfully rebut that preliminary showing.

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[5] For a one-way test, Teva must show that the claims of the '122 patent are rendered obvious by the claims of the '406 patent. Under certain circumstances, a two-way test is applied. A two-way test is applied when an applicant could not have filed all of its claims in one application and Patent Office delays are solely responsible for a second-filed application issuing before a first-filed application. Pursuant to such a test, Teva must show that the claims of the '122 patent are rendered obvious by the claims of the '406 patent and that the claims of the '406 patent are rendered obvious by the claims of the '122 patent.

EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	)	Civil Action No. 04-940 (JJF)

TEVA USA'S STATEMENT OF INTENDED PROOFS

1. Teva USA will offer evidence at trial demonstrating that the asserted claims of the '122 patent are invalid under 35 U.S.C. §§ 102 and 103 because the claimed invention was disclosed in and obvious from the prior art. In addition, Teva USA will prove that the '122 patent is invalid for obviousness-type double patenting in light of U.S. Patent No. 4,761,406 ("the '406 patent"), which was also assigned to Procter & Gamble.

A. Background

2. The asserted claims of the '122 patent relate to a class of diphosphonic acid compositions comprising a pyridine group (a six-membered ring structure in which one of the members is a nitrogen atom and the others are carbon atoms). The patent includes claims to one such compound, 2-(3-pyridyl)-hydroxyethane diphosphonic acid (risedronate, or "3-pyr-EHDP"), as well as to a method of treating diseases associated with abnormal calcium and phosphate metabolism with 3-pyr-EHDP. The '122 patent was not issued until December 10, 1996 (more than 11 years after its filing). The issuance of the '122 patent was delayed by P&G's activities during prosecution,

including the abandonment of claims held to be allowable, the provoking of a patent interference, and failure to prosecute patent claims which were excluded from the interference for several years during the interference and subsequent appeal to the Federal Circuit.

3. P&G filed the application that led to the '122 patent on December 6, 1985 (the '155 application). The '155 application is a continuation-in-part of a patent application filed on December 21, 1985 (the '543 application). On December 6, 1985, when P&G filed the '155 application, P&G had already pending in the U.S. Patent and Trademark Office for six months an application that disclosed various diphosphonic acid compositions, including 2-(2-pyridyl)-hydroxyethane diphosphonic acid ("2-pyr-EHDP"). The only difference between the compound disclosed and whose use was claimed in the '406 patent and risedronate is the location of a nitrogen atom on the pyridine ring. This application eventually issued on August 2, 1988 as the '406 patent, and included claims which specify the use of 2-pyr-EHDP for the treatment of osteoporosis. This patent expired on August 2, 2005.

4. Prior to P&G's filing the '543 application, various other diphosphonic acid compositions were not only known, but were also known to be effective in the treatment of diseases associated with abnormal calcium and phosphate metabolism, such as osteoporosis. Among these earlier known compounds were etidronate, pamidronate, and alendronate.

5. Additionally, at the time of the filing of P&G's '543 application, those of ordinary skill in the art of medicinal chemistry would have had a reasonable expectation that if one pyridyl form was active to treat disease associated with abnormal calcium and

phosphate metabolism, such as osteoporosis, the other two pyridyl forms would likewise be active.

B. Anticipation of Asserted Claims 12, and 14 by the '406 Patent

6. Teva USA does not believe that P&G will be able to demonstrate that the '543 application includes a written description sufficient to support a claim for priority for any of the asserted claims. Teva USA also does not believe that P&G will be able to establish a date of invention for the asserted claims prior to the filing of the'406 application. Accordingly, the '406 patent anticipates asserted claims 12 and 14 of the '122 patent under 35 U.S.C. §102(e) because the '406 patent discloses compounds within the scope of claims 12 and 14, including 2-pyr-EHDP.

C. Obviousness of the Asserted Claims

7. Teva USA will prove that the subject matter of the asserted claims of the '122 patent would have been obvious in light of the '406 patent in combination with other prior art references, including U.S. Patent 3,400,150 (the '150 patent), U.S. Patent 4,473,560 (the '560 patent), U.S. Patent 4,416,877 (the '877 patent), or U.S. Patent 4,267,108 (the '108 patent).

8. As discussed above, the '406 patent is available as prior art under 35 U.S.C. §102(e). As discussed earlier, the '406 patent discloses 2-pyr-EHDP and its use in treating osteoporosis, which is one of many diseases of abnormal calcium and phosphate metabolism. Asserted claims 4, 12, 14 and 16 embrace 3-pyr-EHDP, and asserted claim 23 embraces the use of 3-pyr-EHDP to treat osteoporosis (a disease of abnormal calcium and phosphate metabolism). The only difference between the 2-pyr-EHDP of the '406 patent and the 3-pyr-EHDP of the asserted claims is the location of the

nitrogen in the pyridine ring.. To a medicinal chemist of ordinary skill at the time of the filing of the '122 patent, the disclosure that 2-pyr-EHDP was active would have suggested the 3-pyr-EHDP, and 4-pyr-EHDP, with a reasonable expectation that they would be active as well.

9. In addition to the general knowledge of medicinal chemists related to pyridine compounds, teachings in the prior art regarding various nitrogen-containing bisphosphonates, including pamidronate and alendronate, indicated that variations in the location of the nitrogen in the bisphosphonate would result in compounds that were active. Accordingly, with these teachings (even in the absence of any knowledge of the similarities between different pyridine forms of the same compound), one of ordinary skill in the art presented with the teachings of the '406 patent regarding 2-pyr-EHDP would have been motivated to alter the location of the nitrogen to obtain additional active compounds, e.g., 3-pyr-EHDP, with a reasonable expectation of success.

10. Even without the '406 patent, the subject matter of the asserted claims of the '122 patent would have been obvious. Teva USA will prove that the prior art contained various bisphosphonates containing ring-like structures similar to pyridine. The '150 patent, the '560 patent, the '877 patent and the '108 patent, all disclose compounds extremely similar to 3-pyr-EHDP, and other compounds claimed in the asserted claims. Teva USA will prove that these references in combination with other prior art teachings and knowledge would render the asserted claims obvious to one of ordinary skill in the relevant art.

11. Teva USA does not believe that P&G can establish that any secondary considerations exist, or that any are sufficient, to overcome its showing of obviousness.

D. Obviousness-type Double Patenting of all of the Asserted Claims in Light of Claim 15 of the '406 Patent

12. Even if the '406 patent is not available as a 35 U.S.C. §102(e) reference, claim 15 of that patent renders the asserted claims invalid for obviousness-type double patenting. The '406 patent was filed prior to the '122 application, and issued first. Since the '406 patent was filed first, and issued first, the double patenting analysis employs a "one-way" test. Accordingly, the asserted claims are invalid for obviousness-type double patenting, if the invention of claim 15 of the '406 patent renders the subject matter of the asserted claims obvious.

13. Claim 15 of the '406 patent claims the use of several specific compounds, including 2-pyr-EHDP, for the treatment of osteoporosis.

14. Accordingly, since 3-pyr-EHDP would have been obvious from 2-pyr-EHDP in view of their structural similarity and the knowledge of those skilled in the art relating to such compounds, a person skilled in the art who was aware of the invention of claim 15 of the '406 patent would have found it obvious to make the 3-pyr-EHDP and to use it to treat osteoporosis.

15. Additionally, since as a matter of law secondary considerations of non-obviousness are not relevant to an obviousness-type double patenting evaluation, it is immaterial whether P&G establishes the existence of any such criteria. In any event, P&G cannot establish secondary considerations sufficient to overcome Teva USA's showing of obviousness. For example, P&G cannot establish that the sales success of risedronate is connected with its alleged nonobviousness.